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To: Examiner From: Jackie Pitre

Fax: 571-273-0709 Pages: 43 (including cover sheet)

Re: 5777-00201 Date: June 9, 2005

Phone: 512-853-8891

Re: U.S. Patent Application Serial No. 10/629,538 Entitled: **"STRUCTURAL CAROTENOID ANALOGS FOR THE INHIBITION AND AMELIORATION OF DISEASE"** – Lockwood et al.

Dear Sir,

Pursuant to your request, attached please find the first Office Action for the above-referenced application (mailed January 13, 2005).

If we can be of further assistance, please do not hesitate to call.

Thank you.

UNITED STATES PATENT AND TRADEMARK OFFICE

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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/629,538 | 07/29/2003 | Samuel Fournier Lockwood | 5777-00201/EBM | 6864 |

35690 7590 01/13/2005

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| EXAMINER | |
|---|---|
| WALLER, ROBIN REGINA | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1626 | |

DATE MAILED: 01/13/2005



Please find below and/or attached an Office communication concerning this application or proceeding.

Atty Dkt#: _____ Atty: _____
Transferred ☐ Due Date: 4/13/05
Action: 30 Day ☐ 1Mo. ☐ 2 Mo ☐
3 Mo. ☒ Final Action ☐ Advsy Action ☐
Ntc of Allow ☐ Drawings ☐ Issue Fee ☐
Other: _____
Docketed: 1/18

PTO 90C (Rev. 10/03)

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/629,536 | LOCKWOOD ET AL. | |
| | Examiner | Art Unit | |
| | Robin R. Waller | 1626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *22 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1019-1058* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1019-1058* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08), Paper No(s)/Mail Date *02/05/04,02/02/04,06/25/04, 6/21/04*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Priority*

This application claims priority to Con 10/629,538 filed 07/29/03, which claims benefit of 60/366,194 filed 07/29/02, 60/467,973 filed 05/05/03, 60/472,831, filed 5/22/03,60/473,741 filed 05/28/03, 60,485,304 filed 07/03/03.

### *Information Disclosure Statement*

The information disclosure statements filed 6/25/04, 6/21/04, 2/05/04,2/03/04, 2/02/04 have been acknowledged.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1019-1058 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

1) Nature of invention.

2) State of prior art.

3) Level of ordinary skill in the art.

4) Level of predictability in the art

5) Amount of direction and guidance provided by the inventor.

6) Existence of working examples.

7)Breadth of claims.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

1) Nature of the invention.

Claims 1022,1023,1024,1025,1026,1027,1028 and 1042,1044,1045,1046 and 1047 are directed to carotenoid derivatives of derivatives of naturally occurring carotenoids.

2) State of the prior art.

Carotenoids are amoung the most common natural pigments. The unqiue structure of the carotenoids determines their potential biological functions and actions. (See **Deli et al**). Further in the Specification, on page 22, lines 9-19, Applicants indicate that Carotenoids are as many as 600 in number, have been found in human tissue. However, the prior arts do not describe all carotenoid derivatives of the instant compound.

3) Level of ordinary skill in the art.

The level of skill in the art is high. Due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to

determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Thus, the specification fails to provide sufficient support for the broad use of carotenoids that are derivatives of naturally occurring carotenoid, of the instant compounds.

Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 , states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

4) Level of predictability in the art.

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute

The nature of pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that tho contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

5) Amount of direction and guidance provided by the inventor.

The term derivative may encompass a great number of compounds related to carotenoids, however, without some guidance as to what changes may be made to the carotenoid, there would be little predictability in making and or using such "derivatives of naturally occurring carotenoids". For example there is no guidance as to what modifications may be to specific naturally occurring carotenoids to obtain a derivative. One skilled in the art would not expect any modifications of a naturally occurring carotenoid.

6) Existence of working examples.

Applicant provides limited working examples of how the instant compound is used in Table1 page 105 of the Specification. However, the limited examples do not provide sufficient evidence to support a claim drawn to a method for treating heart disease, such as CAD and CAV. Applicant provides no working examples of a carotenoid derivative as a derivative of naturally occurring derivatives, of the instant compound.

7) Breadth of claims.

Claims 1022,1023,1024,1025,1026,1027,1028 and 1042,1044,1045,1046 and 1047 are extremely broad due to the large number of carotenoid derivatives. Applicant has not provided sufficient evidence to support a claim drawn to carotenoid derivative as a derivative of a naturally occurring carotenoid, of the instant compound.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation.

In view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test how the instant compound is useful in treating a heart disease with no assurance of success. Further the specification fails to provide sufficient support of the broad use of the term derivative. As a result necessitating one of skill in the art to perform an exhaustive search for which derivatives can be prepared In order to practice the claimed invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1019, 1039, 1034 and 1054 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1019 and 1039 the word "comprising is used. This term is open-ended language. This term is best suited for a composition claim. In the instant case, claims 1019 and 1039 are compound claims. Examiner suggests applicant replace the term "comprising" with "consisting of", if applicant intends this claim as a compound claim.

Claims 1034 and 1054 state where in the compound is a part of a composition. This claim does not state which part of the compound is a composition with a formula

and/or a structure. Further, it is not clear whether this claim is intended as a compound claim or a composition claim. The instant claim appears to be a compound claim because a composition claim should have a carrier.

In claim 1019 and 1039 the formula of the derivative was claimed, however in claim 1022 and 1042 applicant states that the "carotenoid derivative is a derivative", however there is no formula associated with the second derivative of the naturally occurring carotenoid. Examiner suggests inserting the formula of all derivatives in present and future claims where pertinent.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Robin Waller whose telephone number is (571) 272-0696. Ms. Waller can normally be reached Monday through Friday 8:30AM to 6:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 703-746-9879.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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